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FIRST NAMED INVENTOR ATTORNEY DOCKET NO. FILING DATE APPLICATION NO. 09/335,581 06/18/99 2016-4010US2 BANNAN J **EXAMINER** HM22/0103 MORGAN AND FINNEGAN LLP MINNIFIELD, N 345 PARK AVENUE **ART UNIT** PAPER NUMBER NEW YORK NY 10154 1645 **DATE MAILED:**

Please find below and/or attached an Office communication concerning this application or pr ceeding.

Commissioner of Patents and Trademarks

01/03/01

Office Action Summary

Application No. 09/335,581

Applicati(s)

BANNAN ET AL

Examiner

N. M. Minnifi Id

Group Art Unit 1645



X Responsive to communication(s) filed on Oct 16, 2000	
☐ This action is FINAL.	
☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quay/0835 C.D. 11; 453 O.G. 213.	
A shortened statutory period for response to this action is set to expire3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).	
Disposition of Claim	
X Claim(s) <u>1-3, 7, 9, 10, and 50-59</u>	is/are pending in the applicat
Of the above, claim(s) <u>1-3, 7, 9, 10, 50-53, and 56-59</u> is/are	e withdrawn from consideration
☐ Claim(s)	is/are allowed.
∑ Claim(s) 54 and 55	is/are rejected.
☐ Claim(s)	is/are objected to.
☐ Claims are subject to rest	triction or election requirement.
Application Papers See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948. The drawing(s) filed on	
Attachment(s) Notice of References Cited, PTO-892 Information Disclosure Statement(s), PTO-1449, Paper No(s)	
SEE OFFICE ACTION ON THE FOLLOWING PAGES	

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DETAILED ACTION

1. Applicants' amendment filed October 16, 2000 is acknowledged and has been entered. Claims 4-6, 8, and 11-49 have been canceled. New claims 50-59 have been added. Claims 50-55 are directed to peptides (Invention I), claims 56 and 57 are directed to pharmaceutical compositions (Invention II), claims 58 and 59 are directed to methods of inducing serum antibodies that bind at least one staphylococcal enterotoxin or streptococcal exotoxin, administering a peptide (Invention III). Based on the previous restriction requirement these claims have grouped as set forth above.

Claims 1-3, 7, 9-10 and 50-59 are now pending in the present application.

2. Applicant's election with traverse of Group I, claims 1-3, 50 and 51-55 and species SEQ ID NO: 3), in Paper No. 8 is acknowledged. The traversal is on the ground(s) that the search for groups I, II and III would not be a serious burden to the Examiner as this type of examination was done in a prior application (08/838413). This is not found persuasive. The Examiner notes that the present restriction requirement is proper; the restriction sets forth the different classifications and the reasons for the different groupings. Prior restriction requirements do not apply to the present application. Applicants requested that multiple sequences be searched and refers the M.P.E.P. 803.04, "Restriction-Nucleotide Sequences" which states that up to 10 independent nucleotide

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sequences can be claimed in a single application. However, the present application claims amino acid sequences, not nucleotide sequences. Further, the species election made be Applicant, SEQ ID NO: 30 was not one of the SEQ ID NOS. set forth in the species election (SEQ ID NO: 28, 29, 3-8). Applicants stated on page 7 of paper No. 8 filed October 16, 2000 that the Examiner has indicated that SEQ 28 is considered generic, however page 6 of the restriction requirement mailed September 12, 2000 indicates that CMYGGTLHEGN is considered generic.

Claims 54 and 55 and this peptide (CMYGGVTEHEGN) will be examined in the pending application. All other claims have been withdrawn from consideration as they are directed to a different invention and/or species. Applicants are requested to set forth specifically defined amino acids with sequence identifiers.

3. Claims 1-3, 7, 9-10, 50-53 and 56-59 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected inventions and/or species, there being no allowable generic or linking claim.

Applicant timely traversed the restriction (election) requirement in Paper No. 8.

The requirement is still deemed proper and is therefore made FINAL.

4. In view of the papers filed October 16, 2000, the inventorship in this nonprovisional application has been changed by the deletion of KUMAR VISVANATHAN.

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The application will be forwarded to the Office of Initial Patent

Examination (OIPE) for issuance of a corrected filing receipt, and correction of
the file jacket and PTO PALM data to reflect the inventorship as corrected.

- 5. Claims 54 and 55 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims should recite that it is either "isolated" or "synthetic", to insure that it is not a product of nature. The claims depend from a nonelected claim.
- 6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- 7. Claims 54 and 55 are rejected under 35 U.S.C. 102(b) as being anticipated by Hoffman et al, 1994; Jett et al, 1994; Soos et al, 1994.

The claims are directed to a peptide comprising the amino acid sequence of CMYGGVTEHEGN and that the sequence is a component of a larger molecule.

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The prior art, for example Soos et al discloses a peptide comprising the claimed amino acid sequence (table 1, p. 598). Hoffman et al discloses a peptide comprising the claimed amino acid sequence (figure 5, p. 3401). Jett et al discloses a peptide comprising the claimed amino acid sequence (table 1, p. 3410).

The prior art peptide appears to be same as that claimed or an obvious variant. The prior art and the claimed invention appear to be the same or an obvious or analogous variant of the peptides claimed by applicants because they appear to possess the same or similar functional characteristics.

Since the Patent Office does not have the facilities for examining and comparing applicants' peptide with the peptide of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed peptide and the peptide of the prior art. See <u>In re Best</u>, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and <u>In re Fitzgerald et al.</u>, 205 USPQ 594. The prior art anticipates the claimed invention.

- 8. No claims are allowed.
- 9. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Iandolo et al discloses a peptide comprising CMYGGVTLHEGN.

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10. The information disclosure statement filed July 19, 1999 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. It is noted that certain references were not found in the prior application (08/848413). These references have not been considered in this application; copies are requested for review.

- 11. The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record in the parent application Serial No. 08/838413.
- 12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is (703) 305-3394. The examiner can normally be reached on Monday-Thursday from 7:00 AM-4:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R. F. Smith, can be reached on (703) 308-3909. The fax phone number for Technology Center 1600 is (703) 308-4556.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 1600 receptionist whose telephone number is (703) 308-0196.

N. M. Minnifield

January 2, 2001

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